

the agency cannot make a determination that it is substantially equivalent to a marketed device, current law requires that the device be automatically classified as a class III—high risk—device, regardless of the actual level of risk posed by the new device. The manufacturer must then either complete costly and time-consuming clinical studies and submit a new device approval application to the agency or must petition the agency for reclassification, which is under current law a complex and time-consuming procedure.

Under my bill, the FDA would be given the statutory flexibility to classify a new device based on the risk posed by the device, at the request of a manufacturer whose device was determined to be "not substantially equivalent" to a marketed device. Under the bill, the FDA would retain full authority for determining the classification of a device. The agency would simply receive a new, risk-based classification option. Since class III devices require the most intensive review, this proposal should free up agency resources to focus on truly high-risk devices.

Second, this legislation will provide the FDA with a much simpler way to recognize device performance standards. Under current law, the FDA has the authority to promulgate standards, but the process for doing so is tortuous. As a result, the agency has rarely used this authority. Under our bill, the agency would retain the authority to promulgate its own standards, but could also recognize national and international performance standards by identifying and listing the standard in the Federal Register. Device manufacturers would then have the option of certifying to the agency that their products met the standard as a way of fulfilling all or part of the applicable statutory requirements which must be met before devices may be marketed. Device performance standards form the basis for device regulation in the European Community. Providing U.S. manufacturers with this option would move forward our efforts to harmonize our regulatory systems.

I would welcome additional cosponsors of this commonsense regulatory reform measure. If you would like further information or would like to cosponsor this legislation, please call me or Jane Williams, 5-3761, of my staff.

TRIBUTE TO KENNETH L. KHACHIGIAN

HON. GEORGE P. RADANOVICH

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 1, 1997

Mr. RADANOVICH. Mr. Speaker, I rise to pay tribute to Kenneth L. Khachigian. A legend in the political arena and a jewel in the Armenian community, Khachigian has joined the Junior Achievement of Armenia's [JAA] Honorary Board.

As noted in the Saturday, March 22 edition of the Armenian Mirror-Spectator (see attached), JAA is an economics and business education program that offers Applied Economics classes and the student company experience in Armenia's high schools and institutions of higher learning. The purpose of the program is to introduce students to the free enterprise system, explain how it operates, and define its role in business and the global

marketplace. Additionally, JAA familiarizes students with the hands-on basics of running a business, and explains to them the importance of economics to their future.

Khachigian, a native of the Central Valley, has had a distinguished career in American politics. A farmer by nature and an attorney by trade, Khachigian has worked for former Presidents Nixon, Reagan, and Bush. In both campaign and executive roles, Khachigian has been instrumental in formulating and implementing the ideals and goals of the Republican Party. In addition to his advisory roles with Presidents Reagan and Bush, Khachigian played an active role in the successful campaigns of California Governors George Deukmejian and Pete Wilson. Most recently, Khachigian served as National Senior Advisor for the Dole for President campaign. In this position, Khachigian coordinated Senate Majority Leader Dole's Presidential bid in the State of California.

Khachigian has also been active outside the political arena. He has served as a member of the board to the Armenian Assembly of America. He also sat as a Presidential appointee on the National Institute of Justice Advisory Board. From 1986-1992, Khachigian served on the Board of Overseers at the Hoover Institution on War, Revolution and Peace. He currently resides on the Board of California Council for Environmental and Economic Balance.

Mr. Speaker, Ken Khachigian is a pioneer in the area of political advising and consulting. Khachigian's numerous accomplishments have been instrumental in advancing the agenda for a more responsible, independent, and productive America. I ask my colleagues to join me in paying tribute to Ken Khachigian, a man of impeccable character. Ken should be admired not only for his multitude of success in America, but also for his tremendous contribution to—and support for—the Armenian community.

KENNETH KHACHIGIAN JOINS JR. ACHIEVEMENT OF ARMENIA'S BOARD

LOS ANGELES, CA—Presidential campaign advisor and political strategist Kenneth L. Khachigian has recently joined Junior Achievement of Armenia's (JAA) Honorary Board, which also includes former California Governor George Deukmejian and Dr. Mihran Agbabian, President Emeritus of the American University of Armenia. The purpose of this distinguished body is to provide JAA with advice, support and guidance.

"I am particularly pleased to become a member of the Honorary Board of Junior Achievement of Armenia. The remarkable and rapid growth of the group has made it among the most successful non-government programs in Armenia," commented Khachigian. "I have great respect for grassroots organizations which promote education and demonstrate a vision for the future, and Junior Achievement of Armenia is just that organization," he said.

Khachigian's career has been highlighted by numerous achievements. Most recently, he served as National Senior Advisor for the Dole for President campaign. In this post, his top priority was coordinating Senator Dole's presidential campaign in the State of California. As a political strategist and advisor, he has led to victory three U.S. Presidents, including Ronald Reagan and George Bush, and several California State leaders, including Governors Pete Wilson and George Deukmejian. During his career, Khachigian has also served as chief speech-writer to President Reagan, and was a Nixon White House aide.

In addition to his professional activities, Khachigian has served as a Board member of the Armenian Assembly of America, and has sat as a Presidential appointee on the National Institute of Justice Advisory Board. During 1986-1992 he served on the Board of Overseers of the Hoover Institution of War, Revolution and Peace at Stanford University. Currently he sits on the Board of the California Council for Environmental and Economic Balance.

Junior Achievement of Armenia is an economics and business education program offering Applied Economics classes and the student company experience in Armenia's high schools, and institutes of higher learning. The program teaches young people how the free enterprise system operates, the role of business in the global marketplace, the hands-on basics of running a business, and the importance of economics on their future. Junior Achievement of Armenia is a non-profit organization.

READING CAN OPEN MANY DOORS

HON. NITA M. LOWEY

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 1, 1997

Mrs. LOWEY. Mr. Speaker, yesterday I joined several of my colleagues in introducing President Clinton's America Reads Challenge Act. This legislation will help mobilize reading specialists and trained volunteers to ensure that every child can read by the end of the third grade.

Today I want to share with the House an essay written by Adam Frankel, the 18-year-old grandson of two of my constituents. Adam writes eloquently about the joys and benefits of reading. As we pledge our efforts to ensure that all children enter fourth grade reading on their own, I thought it might be helpful to hear how one young American uses this gift to learn about the world.

I insert the text of Adam Frankel's essay at this point in the RECORD.

READING CAN OPEN MANY DOORS

(By Adam Frankel)

When I hold a book between my hands, I do not feel the paper and I do not see the words. I feel as though I am holding "knowledge" in my hands, and the more complicated the book, the better. That way, it is not just entertaining, but it is something far more enjoyable: challenging and revealing. After reading and understanding a complicated phrase or book, you feel a sense of accomplishment. When I hold in my hands William James and move my eyes slowly across each word, I know I am looking into the mind of James himself. The words he uses to describe things are as much a part of him as his fingerprint.

When writing, your words build up within and explode out onto paper with your own patent on them. A word can be so much more, if it is allowed to be. The difference between a word's various connotations determine the feeling of a character, or description of a scene. The word can even determine the future of a state, depending on whether it is used correctly or not in policy planning.

Walter Lippman once said that he wrote each sentence as if the article were to be judged on that sentence alone. It is this appreciation of the written word that I try to give to everything I read. And what I have chosen to read has largely defined not only my interests at the moment, but even my